IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRIC OF NORTH CAROLINA
RALEIGH DIVISION
Case No. 15-36

PHYSICIANS HEALTHSOURCE, INC., an Ohio corporation, individually and as the representative of a class of similarly-situated persons, Plaintiff, v. SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD. and JOHN DOES 1-10, Defendants.	)	**COMPLAINT -- CLASS ACTION**

Plaintiff, PHYSICIANS HEALTHSOURCE, INC., ("Plaintiff"), brings this action on behalf of itself and all others similarly situated, through its attorneys, and except as to those allegations pertaining to Plaintiff or its attorneys, which allegations are based upon personal knowledge, alleges the following upon information and belief against Defendants, SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD. and JOHN DOES 1-10 ("Defendants"):

PRELIMINARY STATEMENT

1. This case challenges Defendants' practice of sending unsolicited facsimiles.

2. The federal Telephone Consumer Protection Act of 1991, as amended by the Junk Fax Prevention Act of 2005, 47 USC § 227 ("JFPA" or the "Act"), and the regulations promulgated under the Act, prohibit a person or entity from faxing or having an agent fax advertisements without the recipient's prior express invitation or permission. The JFPA provides a private right of action and provides statutory damages of $500 per violation. Upon information and belief, Defendants have sent facsimile transmissions of unsolicited advertisements to Plaintiff and the Class in violation of the JFPA, including, but not limited to, the facsimile transmissions of seven (7) unsolicited advertisements on or about March 14,

2011, April-May, 2012, May 10, 2012, October 19, 2012, September 30, 2013 and October 8, 2013 ("the Faxes"), true and correct copies of which are attached hereto as Exhibit A, and made a part hereof. The Faxes describe the commercial availability of Defendants' goods and services. Plaintiff is informed and believes, and upon such information and belief avers, that Defendants have sent, and continue to send, unsolicited advertisements via facsimile transmission in violation of the JFPA.

3. Unsolicited faxes damage their recipients. A junk fax recipient loses the use of its fax machine, paper, and ink toner. An unsolicited fax wastes the recipient's valuable time that would have been spent on something else. A junk fax interrupts the recipient's privacy. Unsolicited faxes prevent fax machines from receiving authorized faxes, prevent their use for authorized outgoing faxes, cause undue wear and tear on the recipients' fax machines, and require additional labor to attempt to discern the source and purpose of the unsolicited message.

4. On behalf of itself and all others similarly situated, Plaintiff brings this case as a class action asserting claims against Defendants under the JFPA.

5. Plaintiff is informed and believes, and upon such information and belief avers, that this action is based upon a common nucleus of operative facts because the facsimile transmissions at issue were and are being prepared and sent in the same or similar manner. This action is based on the same legal theory, namely liability under the JFPA. This action seeks relief expressly authorized by the JFPA: (i) injunctive relief enjoining Defendants, their employees, agents, representatives, contractors, affiliates, and all persons and entities acting in concert with them, from sending unsolicited advertisements in violation of the JFPA; (ii) an award of statutory damages in the minimum amount of $500 for each violation of the JFPA, and (iii), the extent that Defendants' violations of the JFPA are shown to be knowing or willful, to have such damages trebled, as provided by § 227(b)(3) of the Act.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 47 U.S.C. § 227.

7. This Court has personal jurisdiction over Defendants because Defendants transact business within this judicial district, have made contacts within this judicial district, and/or have committed tortious acts within this judicial district.

PARTIES

8. Plaintiff, PHYSICIANS HEALTHSOURCE, INC., is an Ohio corporation.

9. On information and belief, Defendant, SALIX PHARMACEUTICALS, INC., is a California corporation with its principal place of business in Raleigh, North Carolina.

10. On information and belief, Defendant, SALIX PHARMACEUTICALS, LTD., is a Delaware corporation with its principal place of business in Raleigh, North Carolina.

11. John Does 1-10 will be identified through discovery, but are not presently known.

FACTS

12. On information and belief, on or about March 14, 2011, April-May, 2012, May 10, 2012, October 19, 2012, September 30, 2013 and October 8, 2013, Defendants transmitted by telephone facsimile machine seven (7) unsolicited advertisements to Plaintiff. Copies of the facsimiles are attached hereto as **Exhibit A**.

13. Plaintiff did not invite or give permission to Defendants to send the faxes.

14. On information and belief, Defendants faxed the same and other unsolicited facsimiles without the required opt out language to Plaintiff and more than 25 other recipients without first receiving the recipients' express permission or invitation.

15. There is no reasonable means for Plaintiff (or any other class member) to avoid receiving unauthorized faxes. Fax machines are left on and ready to receive the urgent communications their owners desire to receive.

16. Defendants' facsimile did not display a proper opt-out notice as required by 47 C.F.R. § 64.1200.

CLASS ACTION ALLEGATIONS

17. In accordance with Fed. R. Civ. P. 23(b)(1), (b)(2) and (b)(3), Plaintiff brings this class action pursuant to the JFPA, on behalf of the following class of persons:

> All persons in the United States who (1) on or after four years prior to the filing of this action until the date of class certification, (2) were sent telephone facsimile messages of material advertising the commercial availability of any property, goods, or services by or on behalf of Defendants, and (3) which did not display a proper opt-out notice.

Excluded from the Class are the Defendants, their employees, agents and members of the Judiciary. Plaintiff reserves the right to amend the class definition upon completion of class certification discovery.

18. Class Size (Fed. R. Civ. P. 23(a)(1)): Plaintiff is informed and believes, and upon such information and belief avers, that the number of persons and entities of the Plaintiff Class is numerous and joinder of all members is impracticable. Plaintiff is informed and believes, and upon such information and belief avers, that the number of class members is more than 100.

19. Commonality (Fed. R. Civ. P. 23 (a) (2)): Common questions of law and fact apply to the claims of all class members. Common material questions of fact and law include, but are not limited to, the following:

a) Whether the Defendants sent unsolicited fax advertisements;

b) Whether the Defendants' faxes advertised the commercial availability of property, goods, or services;

c) The manner and method the Defendants used to compile or obtain the list of fax numbers to which they sent Exhibit A and other unsolicited faxed advertisements;

d) Whether the Defendants faxed advertisements without first obtaining the recipient's prior permission or invitation;

e) Whether the Defendants sent the faxed advertisements knowingly;

f) Whether the Defendants violated the provisions of 47 U.S.C. § 227 and the regulations promulgated thereunder;

g) Whether the faxes contain an "opt-out notice" that complies with the requirements of § (b)(1)(C)(iii) of the Act, and the regulations promulgated thereunder, and the effect of the failure to comply with such requirements;

h) Whether the Defendants should be enjoined from faxing advertisements in the future;

i) Whether the Plaintiff and the other members of the class are entitled to statutory damages; and

j) Whether the Court should award treble damages.

20. Typicality (Fed. R. Civ. P. 23 (a) (3)): The Plaintiff's claims are typical of the claims of all class members. The Plaintiff received the same faxes as the faxes sent by or on behalf of the Defendants advertising goods and services of the Defendants during the Class Period. The Plaintiff is making the same claims and seeking the same relief for itself and all class members based upon the same federal statute. The Defendants have acted in the same or in a similar manner with respect to the Plaintiff and all the class members by sending Plaintiff and each member of the class the same faxes.

21. Fair and Adequate Representation (Fed. R. Civ. P. 23 (a) (4)): The Plaintiff will fairly and adequately represent and protect the interests of the class. It is interested in this matter, has no conflicts and has retained experienced class counsel to represent the class.

22. Need for Consistent Standards and Practical Effect of Adjudication (Fed. R. Civ. P. 23 (b) (1)): Class certification is appropriate because the prosecution of individual actions by class members would: (a) create the risk of inconsistent adjudications that could establish incompatible standards of conduct for the Defendants, and/or (b) as a practical matter, adjudication of the Plaintiff's claims will be dispositive of the interests of class members who are not parties.

23. Common Conduct (Fed. R. Civ. P. 23 (b) (2)): Class certification is also appropriate because the Defendants have acted and refused to act in the same or similar manner with respect to all class members thereby making injunctive and declaratory relief appropriate. The Plaintiff demands such relief as authorized by 47 U.S.C. §227.

24. Predominance and Superiority (Fed. R. Civ. P. 23 (b) (3)): Common questions of law and fact predominate over any questions affecting only individual members, and a class action is superior to other methods for the fair and efficient adjudication of the controversy because:

a) Proof of the claims of the Plaintiff will also prove the claims of the class without the need for separate or individualized proceedings;

b) Evidence regarding defenses or any exceptions to liability that the Defendants may assert and attempt to prove will come from the Defendants' records and will not require individualized or separate inquiries or proceedings;

c) The Defendants have acted and are continuing to act pursuant to common policies or practices in the same or similar manner with respect to all class members;

d) The amount likely to be recovered by individual class members does not support individual litigation. A class action will permit a large number of relatively small claims

involving virtually identical facts and legal issues to be resolved efficiently in one (1) proceeding based upon common proofs; and

e) This case is inherently manageable as a class action in that:

(i) The Defendants identified persons or entities to receive the fax transmissions and it is believed that the Defendants' computer and business records will enable the Plaintiff to readily identify class members and establish liability and damages;

(ii) Liability and damages can be established for the Plaintiff and the class with the same common proofs;

(iii) Statutory damages are provided for in the statute and are the same for all class members and can be calculated in the same or a similar manner;

(iv) A class action will result in an orderly and expeditious administration of claims and it will foster economics of time, effort and expense;

(v) A class action will contribute to uniformity of decisions concerning the Defendants' practices; and

(vi) As a practical matter, the claims of the class are likely to go unaddressed absent class certification.

Claim for Relief for Violation of the JFPA, 47 U.S.C. § 227 *et seq.*

25. All Paragraphs of the Complaint are incorporated herein by reference.

26. The JFPA makes it unlawful for any person to "use any telephone facsimile machine, computer or other device to send, to a telephone facsimile machine, an unsolicited advertisement . . . ." 47 U.S.C. § 227(b)(1)(C).

27. The JFPA defines "unsolicited advertisement" as "any material advertising the

commercial availability or quality of any property, goods, or services which is transmitted to any person without that person's prior express invitation or permission, in writing or otherwise." 47 U.S.C. § 227 (a) (5).

28. **Opt-Out Notice Requirements.** The JFPA strengthened the prohibitions against the sending of unsolicited advertisements by requiring, in § (b)(1)(C)(iii) of the Act, that senders of faxed advertisements place a clear and conspicuous notice on the first page of the transmission that contains the following among other things (hereinafter collectively the "Opt-Out Notice Requirements"):

a) a statement that the recipient is legally entitled to opt-out of receiving future faxed advertisements – knowing that he or she has the legal right to request an opt-out gives impetus for recipients to make such a request, if desired;

b) a statement that the sender must honor a recipient's opt-out request within 30 days and the sender's failure to do so is unlawful – thereby encouraging recipients to opt-out, if they did not want future faxes, by advising them that their opt-out requests will have legal "teeth";

c) a statement advising the recipient that he or she may opt-out with respect to all of his or her facsimile telephone numbers and not just the ones that receive a faxed advertisement from the sender – thereby instructing a recipient on how to make a valid opt-out request for all of his or her fax machines.

The requirement of (a) above is incorporated from § (b)(D)(ii) of the Act. The requirement of (b) above is incorporated from § (b)(D)(ii) of the Act and the rules and regulations of the Federal Communications Commission (the "FCC") in ¶ 31 of its 2006 Report and Order (*In the Matter of Rules and Regulations Implementing the Telephone Consumer*

Protection Act, Junk Prevention Act of 2005, 21 F.C.C.R. 3787, 2006 WL 901720, which rules and regulations took effect on August 1, 2006). The requirements of (c) above are contained in § (b)(2)(E) of the Act and incorporated into the Opt-Out Notice Requirements via § (b)(2)(D)(ii). Compliance with the Opt-Out Notice Requirements is neither difficult nor costly. The Opt-Out Notice Requirements are important consumer protections bestowed by Congress upon the owners of the telephone lines and fax machines giving them the right, and means, to stop unwanted faxed advertisements.

29. **2006 FCC Report and Order.** The JFPA, in § (b)(2) of the Act, directed the FCC to implement regulations regarding the JFPA, including the JFPA's Opt-Out Notice Requirements and the FCC did so in its 2006 Report and Order, which in addition provides among other things:

a) The definition of, and the requirements for, an established business relationship for purposes of the first of the three prongs of an exemption to liability under § (b)(1)(C)(i) of the Act and provides that the lack of an "established business relationship" precludes the ability to invoke the exemption contained in § (b)(1)(C) of the Act (*See* 2006 Report and Order ¶¶ 8-12 and 17-20);

b) The required means by which a recipient's facsimile telephone number must be obtained for purposes of the second of the three prongs of the exemption under § (b)(1)(C)(ii) of the Act and provides that the failure to comply with these requirements precludes the ability to invoke the exemption contained in § (b)(1)(C) of the Act (*See* 2006 Report and Order ¶¶ 13-16);

c) The things that must be done in order to comply with the Opt-Out Notice Requirements for the purposes of the third of the three prongs of the exemption under §

(b)(1)(C)(iii) of the Act and provides that the failure to comply with these requirements precludes the ability to invoke the exemption contained in § (b)(1)(C) of the Act (*See* 2006 Report and Order ¶¶ 24-34);

d) The failure of a sender to comply with the Opt-Out Notice Requirements precludes the sender from claiming that a recipient gave "prior express permission or invitation" to receive the sender's fax (*See* Report and Order ¶ 48);

As a result thereof, a sender of a faxed advertisement who fails to comply with the Opt-Out Notice Requirements has, by definition, transmitted an unsolicited advertisement under the JFPA. This is because such a sender can neither claim that the recipients of the faxed advertisement gave "prior express permission or invitation" to receive the fax nor can the sender claim the exemption from liability contained in § (b)(C)(1) of the Act.

30. **The Faxes**. Defendants, upon information and belief, sent on or about March 14, 2011, April-May, 2012, May 10, 2012, October 19, 2012, September 30, 2013 and October 8, 2013, advertisements via facsimile transmission from telephone facsimile machines, computers, or other devices to the telephone lines and facsimile machines of Plaintiff and members of the Plaintiff Class. The Faxes constituted an advertisement under the Act. Defendants failed to comply with the Opt-Out Requirements in connection with the Faxes. The Faxes were transmitted to persons or entities without their prior express permission or invitation and/or Defendants are precluded from asserting any prior express permission or invitation because of the failure to comply with the Opt-Out Notice Requirements.

31. Defendants violated the JFPA and the regulations promulgated thereunder by sending the Faxes via facsimile transmission to Plaintiff and members of the Class.

32. **Defendants' Other Violations.** Plaintiff is informed and believes, and upon such information and belief avers, that during the period preceding four years of the filing of this

Complaint and repeatedly thereafter, Defendants have sent via facsimile transmission from telephone facsimile machines, computers, or other devices to telephone facsimile machines of members of the Plaintiff Class faxes that constitute advertisements under the JFPA that were transmitted to persons or entities without their prior express permission or invitation (and/or that Defendants are precluded from asserting any prior express permission or invitation because of the failure to comply with the Opt-Out Notice Requirements in connection with such transmissions). By virtue thereof, Defendants violated the JFPA and the regulations promulgated thereunder.

33. Plaintiff is informed and believes, and upon such information and belief avers, that Defendants may be continuing to send unsolicited advertisements via facsimile transmission in violation of the JFPA and the regulations promulgated thereunder, and absent intervention by this Court, will do so in the future.

34. The TCPA/JFPA provides a private right of action to bring this action on behalf of Plaintiff and the Plaintiff Class to redress Defendants' violations of the Act, and provides for statutory damages. 47 U.S.C. § 227(b)(3). The Act also provides that injunctive relief is appropriate. *Id.*

35. The JFPA is a strict liability statute, so the Defendants are liable to the Plaintiff and the other class members even if their actions were only negligent.

36. The Defendants knew or should have known that (a) the Plaintiff and the other class members had not given express invitation or permission for the Defendants or anybody else to fax advertisements about the Defendants' goods or services; (b) the Plaintiff and the other class members did not have an established business relationship; (c) Defendants transmitted

advertisements; (d) the Faxes did not contain the required Opt-Out Notice; and (e) Defendants' transmission of advertisements that did not contain the required opt-out notice was unlawful.

37. The Defendants' actions caused damages to the Plaintiff and the other class members. Receiving the Defendants' junk faxes caused the recipients to lose paper and toner consumed in the printing of the Defendants' faxes. Moreover, the Defendants' faxes used the Plaintiff's and the other class members' telephone lines and fax machine. The Defendants' faxes cost the Plaintiff and the other class members time, as the Plaintiff and the other class members and their employees wasted their time receiving, reviewing and routing the Defendants' unauthorized faxes. That time otherwise would have been spent on the Plaintiff's and the other class members' business activities. The Defendants' faxes unlawfully interrupted the Plaintiff's and other class members' privacy interests in being left alone. Finally, the injury and property damage sustained by Plaintiff and the other class members from the sending of Defendants' advertisements occurred outside of Defendants' premises.

WHEREFORE, Plaintiff, PHYSICIANS HEALTHSOURCE, INC., individually and on behalf of all others similarly situated, demands judgment in its favor and against Defendants, SALIX PHARMACEUTICALS, INC. and SALIX PHARMACEUTICALS, LTD., jointly and severally, as follows:

A. That the Court adjudge and decree that the present case may be properly maintained as a class action, appoint the Plaintiff as the representative of the class, and appoint the Plaintiff's counsel as counsel for the class;

B. That the Court award actual monetary loss from such violations or the sum of five hundred dollars ($500.00) for each violation, whichever is greater;

C. That Court enjoin the Defendants from additional violations; and

D. That the Court award pre-judgment interest, costs, and such further relief as the Court may deem just and proper.

Respectfully submitted, this the 22nd day of January, 2015.

HIGGINS BENJAMIN, PLLC, individually and as the representative of a class of similarly-situated persons,

By: **/s/ John F. Bloss**
John F. Bloss

John F. Bloss
N.C. State Bar # 23947
Higgins Benjamin, PLLC
101 W. Friendly Ave., Ste. 500
Greensboro, NC 27401
Telephone: 336-273-1600
Fax: 336-274-4650
JBloss@greensborolaw.com

Brian J. Wanca
Ryan M. Kelly
ANDERSON + WANCA
3701 Algonquin Road, Suite 760
Rolling Meadows, IL 60008
Telephone: 847-368-1500
Fax: 847-368-1501
bwanca@andersonwanca.com
rkelly@andersonwanca.com

WEBCAST

To effectively maintain remission, transition your UC patients to low cost Apriso 1.5 g

apriso (mesalamine) 0.375g
EXTENDED-RELEASE CAPSULES

Salix Pharmaceuticals, Inc. cordially invites you to attend an interactive Webcast meeting

Presented by

Ellen J. Scherl, MD, FACP
Director, Jill Roberts Center for Inflammatory Bowel Disease
Jill Roberts Associate Professor of Clinical Medicine
Weill Medical College of Cornell University
Associate Attending Physician
New York Presbyterian Hospital
New York, NY

MAR 14 2011

Tuesday, March 15th, 2011
Reception at 6:30 PM ET and Webcast Presentation at 7:00 PM ET

Carlo & Johnny
9769 Montgomery Road
Cincinnati, OH 45242
(513) 936-8600

TO REGISTER: Complete the form below and fax back to (201) 288-2307 or
Call the program registration line at (877) 963 3532

Last Name _____ First Name _____ M.I. _____ Degree/Specialty _____

Address (No PO Boxes) _____ City/State/ZIP _____

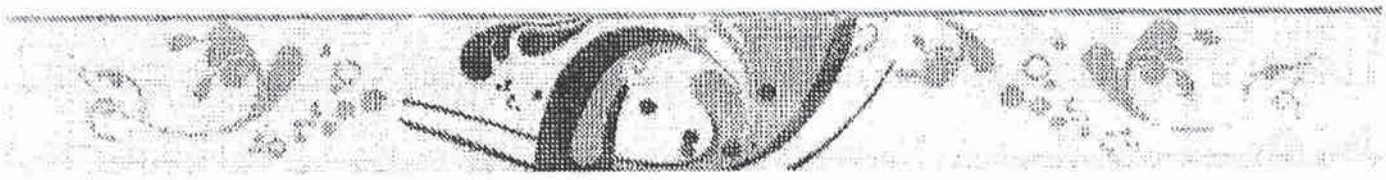
Phone Number _____ Fax Number _____

Email Address _____

In accordance with the PhRMA Code on Interactions with Healthcare Professionals, attendance at this educational program is limited to healthcare professionals. Accordingly, attendance by guests or spouses is not appropriate. If you are licensed in any state or other jurisdiction (eg, MA, VT, MN) or are an employee or contractor of any organization or governmental entity that limits or prohibits meals from pharmaceuticals companies, please identify yourself so that you (and we) are able to comply with such requirements. Your name, the value, and the purpose of any educational item, meal, or other items of value you received may be reported as required by state or federal law. Once reported, this information may be publicly accessible.

To be removed from the fax list for this program, please initial here ____ and fax this form to (201) 288-2307 or call (877) 963-3532. All requests to be removed from this fax list must also identify the fax number to be removed. Our failure to comply with the request in the shortest reasonable time established by the FCC is unlawful.

UC = Ulcerative Colitis



WEBCAST

To effectively maintain remission, transition your UC patients to low cost Apriso 1.5 g

apriso (mesalamine) 0.375g EXTENDED-RELEASE CAPSULES

Salix Pharmaceuticals, Inc. cordially invites you to attend an interactive Webcast meeting

Presented by

Ellen J. Scherl, MD, FACP
Director, Jill Roberts Center for Inflammatory Bowel Disease
Jill Roberts Associate Professor of Clinical Medicine
Weill Medical College of Cornell University
Associate Attending Physician
New York Presbyterian Hospital
New York, NY

Tuesday, March 15th, 2011
Reception at 6:30 PM ET and Webcast Presentation at 7:00 PM ET

Carlo & Johnny
9769 Montgomery Road
Cincinnati, OH 45242
(513) 936-8600

TO REGISTER: Complete the form below and fax back to (201) 288-2307 or
Call the program registration line at (877) 963 3532

MAR 14 2011

Last Name | First Name | M.I. | Degree/Specialty

Address (No PO Boxes) | City/State/ZIP

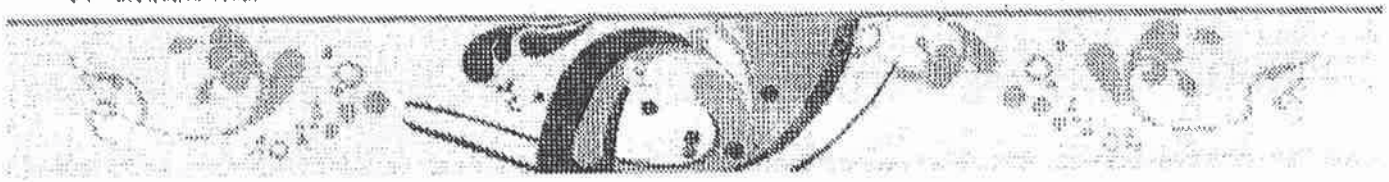
Phone Number | Fax Number

Email Address

In accordance with the PhRMA Code on Interactions with Healthcare Professionals, attendance at this educational program is limited to healthcare professionals. Accordingly, attendance by guests or spouses is not appropriate. If you are licensed in any state or other jurisdiction (eg, MA, VT, MN) or are an employee or contractor of any organization or governmental entity that limits or prohibits meals from pharmaceuticals companies, please identify yourself so that you (and we) are able to comply with such requirements. Your name, the value, and the purpose of any educational item, meal, or other items of value you received may be reported as required by state or federal law. Once reported, this information may be publicly accessible.

To be removed from the fax list for this program, please initial here ____ and fax this form to (201) 288-2307 or call (877) 963-3532. All requests to be removed from this fax list must also identify the fax number to be removed. Our failure to comply with the request in the shortest reasonable time established by the FCC is unlawful.

UC = Ulcerative Colitis



Please join us at the **Solesta® DDW Hands-On Station**

at the ASGE Learning Center located in Exhibit Hall H of the San Diego Convention Center in San Diego, CA.

Saturday, May 19	Sunday, May 20	Monday, May 21	Tuesday, May 22
11:00 am - 1:00 pm	11:00 am - 1:00 pm	1:30 pm - 3:30 pm	11:00 am - 1:00 pm

Fecal incontinence affects 15% of people in the US over the age of 50 and is a leading reason for admission to assisted living facilities. It is one of the most psychologically and socially debilitating conditions in an otherwise healthy individual. Many patients try to manage the problem themselves, and in others conservative approaches (dietary modification, anti-motility agents) do not work. Solesta is a minimally invasive, outpatient treatment developed to address the gap between conservative therapies and surgery.

The Solesta Hands-on Station, sponsored by Salix Pharmaceuticals, Inc., will provide participants with important product information, proper syringe assembly instructions, hands-on injection technique training and post procedure patient care information.

For greater control over **FECAL INCONTINENCE**

Solesta®

A quick, nonsurgical injectable option— an outpatient procedure without anesthesia

---

Important Safety Information

Indication

Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, anti-motility medications).

Contraindications

Solesta is contraindicated in patients with active inflammatory bowel disease, immunodeficiency disorders or ongoing immunosuppressive therapy, previous radiation treatment to the pelvic area, significant mucosal or full thickness rectal prolapse, active proctitis or other infections in the anorectal region, anorectal atresia, tumors, or malformation, rectocele, rectal varices, presence of existing implant (other than Solesta) in anorectal region, or allergy to hyaluronic acid-based products.

Warnings

Do not inject Solesta intravascularly. Injection of Solesta into blood vessels may cause vascular occlusion. Injection in the midline of the anterior wall of the rectum should be avoided in men with an enlarged prostate.

Precautions

Solesta should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure.

The safety and effectiveness of Solesta have not been investigated in patients with complete external sphincter disruption or significant chronic anorectal pain.

The safety and effectiveness of Solesta have not been investigated in patients with previous procedures involving the anorectal region: rectal anastomosis < 12 cm from the anal verge, anorectal surgery within the previous 12 months, hemorrhoid treatment with a rubber band within 3 months, anorectal implants and previous injection therapy, Stapled Transanal Rectal Resection (STARR), or stapled hemorrhoidectomy.

The safety and effectiveness of Solesta have not been tested in patients under the age of 18 years. The safety and effectiveness of Solesta have not been studied in pregnant or breastfeeding women.

Adverse Events

In the Pivotal study, a total of 232 treatment-related adverse events for either Solesta or sham were reported for up to 18 months after treatment. Of these, 3 (1.3%) were deemed serious by the investigators. These serious adverse events, assessed as related to Solesta, occurred in 3 patients, including 1 case of E. Coli bacteremia and 2 cases of rectal abscess (1 event per patient). All serious adverse events resolved without any sequelae following treatment.

Overall, 96% of the 203 Solesta treatment-related adverse events were of mild to moderate intensity, and 97% of the events required no intervention or required medical or simple noninvasive interventions.

The Open-Label and Proof-of-Concept studies demonstrated similar safety results as the Pivotal study. The adverse event profile of Solesta beyond 24 months1 is not known but is under investigation in post-marketing studies.

For Complete Prescribing Information, please visit **www.solestainfo.com.**

Salix Pharmaceuticals, Inc

Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, antimotility medications).

Solesta®
www.solestainfo.com

Please join us at the **Solesta® DDW Hands-On Station**

at the ASGE Learning Center located in Exhibit Hall H of the San Diego Convention Center in San Diego, CA.

Saturday, May 19	Sunday, May 20	Monday, May 21	Tuesday, May 22
11:00 am - 1:00 pm	11:00 am - 1:00 pm	1:30 pm - 3:30 pm	11:00 am - 1:00 pm

Fecal incontinence affects 15% of people in the US over the age of 50 and is a leading reason for admission to assisted living facilities. It is one of the most psychologically and socially debilitating conditions in an otherwise healthy individual. Many patients try to manage the problem themselves, and in others conservative approaches (dietary modification, anti-motility agents) do not work. Solesta is a minimally invasive, outpatient treatment developed to address the gap between conservative therapies and surgery.

The Solesta Hands-on Station, sponsored by Salix Pharmaceuticals, Inc., will provide participants with important product information, proper syringe assembly instructions, hands-on injection technique training and post procedure patient care information.

MAY 10 2012

For greater control over **FECAL INCONTINENCE**

Solesta®

A quick, nonsurgical injectable option—
an outpatient procedure without anesthesia

Important Safety Information

Indication
Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, anti-motility medications).

Contraindications
Solesta is contraindicated in patients with active inflammatory bowel disease, immunodeficiency disorders or ongoing immunosuppressive therapy, previous radiation treatment to the pelvic area, significant mucosal or full thickness rectal prolapse, active proctitis or other infections in the anorectal region, anorectal atresia, tumors, or malformation, rectocele, rectal varices, presence of existing implant (other than Solesta) in anorectal region, or allergy to hyaluronic acid-based products.

Warnings
Do not inject Solesta intravascularly. Injection of Solesta into blood vessels may cause vascular occlusion. Injection in the midline of the anterior wall of the rectum should be avoided in men with an enlarged prostate.

Precautions
Solesta should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure.

The safety and effectiveness of Solesta have not been investigated in patients with complete external sphincter disruption or significant chronic anorectal pain.

The safety and effectiveness of Solesta have not been investigated in patients with previous procedures involving the anorectal region: rectal anastomosis < 12 cm from the anal verge, anorectal surgery within the previous 12 months, hemorrhoid treatment with a rubber band within 3 months, anorectal implants and previous injection therapy, Stapled Transanal Rectal Resection (STARR), or stapled hemorrhoidectomy.

The safety and effectiveness of Solesta have not been tested in patients under the age of 18 years. The safety and effectiveness of Solesta have not been studied in pregnant or breastfeeding women.

Adverse Events
In the Pivotal study, a total of 232 treatment-related adverse events for either Solesta or sham were reported for up to 18 months after treatment. Of these, 3 (1.3%) were deemed serious by the investigators. These serious adverse events, assessed as related to Solesta, occurred in 3 patients, including 1 case of E. Coli bacteremia and 2 cases of rectal abscess (1 event per patient). All serious adverse events resolved without any sequelae following treatment.

Overall, 96% of the 203 Solesta treatment-related adverse events were of mild to moderate intensity, and 97% of the events required no intervention or required medical or simple noninvasive interventions.

The Open-Label and Proof-of-Concept studies demonstrated similar safety results as the Pivotal study. The adverse event profile of Solesta beyond 24 months1 is not known but is under investigation in post-marketing studies.

For Complete Prescribing Information, please visit **www.solestainfo.com.**

Salix Pharmaceuticals, Inc

Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, antimotility medications).

Solesta®
www.solestainfo.com

Please join us at the

Solesta® ACG Hands-On Workshop

Classroom 4 of the Hands-On Workshop Center located in Hall B of the Sands Expo Center
Access to the Sands Expo on Level 2 of the Venetian, Las Vegas, NV

Sunday, October 21	Monday, October 22
3:30 pm – 7:00 pm	8:00 am – 4:30 pm

The Solesta hands-on station will give participants the opportunity to simulate the Solesta procedure utilizing a porcine model through the direction of Jorge Marcet, MD, University of South Florida Morsani College of Medicine; Jaime Sanchez, MD, University of South Florida Morsani College of Medicine; and Mitchell Bernstein, MD, New York University Langone Medical Center.

Fecal incontinence affects 15 million people in the US and is a leading reason for admission to assisted living facilities. It is one of the most psychologically and socially debilitating conditions in an otherwise healthy individual. Many patients try to manage the problem themselves, and in others conservative approaches (dietary modification, anti-motility agents) do not work. Solesta is a minimally invasive, outpatient treatment developed to address the gap between conservative therapies and surgery.

For greater control over **FECAL INCONTINENCE**

Solesta®

A quick, nonsurgical injectable option—
an outpatient procedure without anesthesia

Important Safety Information

SOLESTA is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, anti-motility medications).

SOLESTA is contraindicated in patients with active inflammatory bowel disease, immunodeficiency disorders or ongoing immunosuppressive therapy, previous radiation treatment to the pelvic area, significant mucosal or full thickness rectal prolapse, active proctitis or other infections in the anorectal region, anorectal atresia, tumors, or malformation, rectocele, rectal varices, presence of existing implant (other than SOLESTA) in anorectal region, or allergy to hyaluronic acid-based products.

SOLESTA must not be injected intravascularly as injection of SOLESTA into blood vessels may cause vascular occlusion. Injection in the midline of the anterior wall of the rectum should be avoided in men with an enlarged prostate.

SOLESTA should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program in the SOLESTA injection procedure.

The most common adverse reactions with SOLESTA (incidence >2%) are proctalgia, anorectal hemorrhage, injection site hemorrhage, pyrexia, injection site pain, diarrhea, and anorectal discomfort.

For Complete Prescribing Information, please visit **www.solestainfo.com.**

Salix

Solesta
www.solestainfo.com

RECEIVED SEP 3 0 2013

Solesta®

Please join us at the

Solesta® ACG Hands-On Workshop

15-minute training

Classroom 5 of the Hands-On Workshop Center located in the Exhibit Hall of the San Diego Convention Center

Sunday, October 13	Monday, October 14
3:30 pm - 7:00 pm	10:00 am - 4:30 pm

The Solesta® Porcine Model Training, sponsored by Salix Pharmaceuticals, Inc., will provide participants with important product information, proper syringe assembly instructions, hands-on injection technique training and post procedure patient care information.

For control over **FECAL INCONTINENCE**

Solesta®

A quick, nonsurgical injectable option—
an outpatient procedure without anesthesia

Indication
Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, antimotility medications).

Important Safety Information
SOLESTA® (hyaluronic acid/dextranomer) is contraindicated in patients with active inflammatory bowel disease, immunodeficiency disorders or ongoing immunosuppressive therapy, previous radiation treatment to the pelvic area, significant mucosal or full thickness rectal prolapse, active anorectal conditions (including abscess, fissures, sepsis, bleeding, proctitis, or other infections) , anorectal atresia, tumors, or malformation, rectocele, rectal varices, presence of existing implant (other than SOLESTA) in anorectal region, or allergy to hyaluronic acid-based products.

SOLESTA must not be injected intravascularly as injection of SOLESTA into blood vessels may cause vascular occlusion. Injection in the midline of the anterior wall of the rectum should be avoided in men with an enlarged prostate.

SOLESTA should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program on the SOLESTA injection procedure.

The most common adverse reactions with SOLESTA (incidence >4%) in the clinical study were proctalgia, anorectal hemorrhage, injection site hemorrhage, pyrexia, injection site pain, diarrhea, and anorectal discomfort.

Please see complete Prescribing Information for SOLESTA.

Please see following Brief Summary.
For Complete Prescribing Information, please visit **www.solestainfo.com**.

Salix Pharmaceuticals, Inc.

Solesta®
www.solestainfo.com

Solesta®

Brief Summary
Please consult Package Insert for full prescribing information.

Indication for Use
Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, antimotility medications).

Contraindications
Solesta is contraindicated in patients with the following conditions:

- Active inflammatory bowel disease
- Immunodeficiency disorders or ongoing immunosuppressive therapy
- Previous radiation treatment to the pelvic area
- Significant mucosal or full thickness rectal prolapse
- Active anorectal conditions including: abscess, fissures, sepsis, bleeding, proctitis, or other infections
- Anorectal atresia, tumors, stenosis or malformation
- Rectocele
- Rectal varices
- Presence of existing implant (other than Solesta) in anorectal region
- Allergy to hyaluronic acid–based products

Warnings
- Do not inject Solesta intravascularly. Injection of Solesta into blood vessels may cause vascular occlusion.
- Injection in the midline of the anterior wall of the rectum should be avoided in men with enlarged prostate.

Precautions
General precautions
- Solesta should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure.
- The safety and effectiveness of Solesta have not been investigated in patients with complete external sphincter disruption or significant chronic anorectal pain.
- The safety and effectiveness of Solesta have not been investigated in patients with previous procedures involving the anorectal region: rectal anastomosis <12 cm from anal verge, anorectal surgery within previous 12 months, hemorrhoid treatment with rubber band within 3 months, anorectal implants and previous injection therapy, Stapled Transanal Rectal Resection (STARR) or stapled hemorrhoidectomy.
- The safety and effectiveness of Solesta have not been studied in patients under the age of 18 years.
- The safety and effectiveness of Solesta have not been studied in pregnant or breastfeeding women.
- The durability of Solesta has not been studied past 12 months.
- The safety and effectiveness of Solesta have been studied in patients who received one or two treatments. In the Pivotal study, the majority of patients received two treatments, four weeks apart.

Patient related precautions
- Patients with bleeding diathesis or patients using anticoagulant or antiplatelet agents, as with any injections, may experience increased bleeding at injection sites.
- Patients should be counseled that a repeated Solesta injection procedure may be required to achieve a satisfactory level of improvement in incontinence.

Procedure related precautions
- Adequate bowel preparation of the rectum using enema is required prior to injection. The enema should be given immediately prior to the procedure to ensure evacuation of the anorectum. It is recommended that additional cleansing of the injection area with an antiseptic be performed prior to injection. Use of prophylactic antibiotics is recommended.
- Solesta should be injected slowly to avoid undue stress on the Luer-lock connection which could cause leakage of the gel.
- After injection of Solesta, hold the needle at the injection site for an additional 15-30 seconds to minimize leakage of Solesta.
- Injections too close to the dentate line or too deep in the tissue might cause excessive pain.
- Injection should be stopped if excessive bleeding or pain occurs.
- One sterile needle should be used per syringe and injection.

Device related precautions
- The use of needles other than those supplied may impede injection of Solesta due to the properties of the gel and may cause device malfunction.
- Solesta is supplied ready to use in a prefilled syringe with a Luer-lock fitting. Carefully examine the unit to verify that neither the contents nor the package has been damaged in shipment. Do not use if damaged.
- Solesta is supplied sterile and is intended for single use only. Do not re-sterilize, as this may damage or alter the product.
- In the event of accidental contamination of a needle, discard the needle.
- Never mix Solesta with other products.
- Solesta is to be stored at up to 25°C (77°F), and used prior to the expiration date printed on the label. Do not expose Solesta to either sunlight or freezing, as this may damage or alter the product.
- Care should be taken when handling the glass syringes and disposing of broken glass to avoid laceration or other injury.
- After use, syringes and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, state and federal requirements.

Adverse Events

Potential adverse events include: abdominal discomfort, abdominal distension, abdominal pain, lower abdominal pain, abdominal rigidity, alopecia, anal abscess, anal fissure, anal hemorrhage, anal prolapse, anal pruritus, anorectal discomfort, back pain, constipation, C-reactive protein increased, chills, cold sweat, defecation urgency, dermatitis, diarrhea, device dislocation, dizziness, dyspareunia, escherichia bacteremia, fecal incontinence, feces hard, fatigue, gastrointestinal motility disorder, gastrointestinal pain, genital discharge, genital prolapse, hematochezia, hematospermia, hemorrhoids, infection, injection site abscess, injection site discomfort, injection site hemorrhage, injection site hematoma, injection site inflammation, injection site irritation, injection site nodule, injection site pain, injection site pustule, injection site swelling, injection site ulcer, intestinal mass, malaise, mucosal inflammation, musculoskeletal pain, perineal abscess, nausea, edema, pain, painful defecation, pelvic mass, perineal pain, proctalgia, proctitis, pyrexia, rectal abscess, rectal discharge, rectal hemorrhage, rectal lesion, rectal obstruction, rectal prolapse, rectal spasm, rectal tenesmus, rectovaginal septum abscess, urinary retention, vaginal discharge, vulvovaginal pain. The adverse event profile of Solesta beyond 24 months* is not known, but is under investigation in post-market studies.

The safety evaluation of Solesta in the treatment of fecal incontinence (FI) is based on the results from the Pivotal Clinical study, and is supported by the Open-Label multicenter clinical study and one single site Proof-of-Concept study. The analysis of safety was based on the safety cohort of all 206 patients treated in the Pivotal Study with either Solesta or Sham. Safety data for Solesta are available from 359 treatments in 197 total patients followed for up to 18 months post treatment (ie, 136 subjects from the blinded phase and 61 subjects from the open phase).

Directions for Use
Solesta should be administered by qualified physicians with experience in the treatment of anorectal conditions and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure. Solesta should only be used after a thorough physical evaluation of the patient to exclude treatable underlying disorders.

Please consult Package Insert for full directions for use and method of administration.

How Supplied
Solesta is supplied in a glass syringe with a standard Luer-lock fitting containing 1 mL gel. Each syringe is terminally moist heat sterilized in a pouch. Four pouches, each containing one syringe are packed in a carton together with five Sterican needles (21 G x 4¾ inches, 0.80 mm x 120 mm), patient record labels and a Package Insert. The needles are sterilized by ethylene oxide.

Storage
Store at a temperature up to 25°C (77°F) and protect from sunlight and freezing.

06/11

*Safety information presented in the Package Insert only includes data up to 18 months.

Solesta is a registered trademark of Q-Med AB.

Salix Pharmaceuticals, Inc.

SOL12/57

Solesta®

Please join us at the

Solesta® ACG Hands-On Workshop

15-minute training

Classroom 5 of the Hands-On Workshop Center located in the Exhibit Hall of the San Diego Convention Center

RECEIVED

Sunday, October 13	Monday, October 14
3:30 pm - 7:00 pm	10:00 am - 4:30 pm

The Solesta® Porcine Model Training, sponsored by Salix Pharmaceuticals, Inc., will provide participants with important product information, proper syringe assembly instructions, hands-on injection technique training and post procedure patient care information.

For control over **FECAL INCONTINENCE**

Solesta®

A quick, nonsurgical injectable option— an outpatient procedure without anesthesia

Indication

Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, antimotility medications).

Important Safety Information

SOLESTA® (hyaluronic acid/dextranomer) is contraindicated in patients with active inflammatory bowel disease, immunodeficiency disorders or ongoing immunosuppressive therapy, previous radiation treatment to the pelvic area, significant mucosal or full thickness rectal prolapse, active anorectal conditions (including abscess, fissures, sepsis, bleeding, proctitis, or other infections) , anorectal atresia, tumors, or malformation, rectocele, rectal varices, presence of existing implant (other than SOLESTA) in anorectal region, or allergy to hyaluronic acid-based products.

SOLESTA must not be injected intravascularly as injection of SOLESTA into blood vessels may cause vascular occlusion. Injection in the midline of the anterior wall of the rectum should be avoided in men with an enlarged prostate.

SOLESTA should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program on the SOLESTA injection procedure.

The most common adverse reactions with SOLESTA (incidence >4%) in the clinical study were proctalgia, anorectal hemorrhage, injection site hemorrhage, pyrexia, injection site pain, diarrhea, and anorectal discomfort.

Please see complete Prescribing Information for SOLESTA.

Please see following Brief Summary.
For Complete Prescribing Information, please visit **www.solestainfo.com**.

Salix Pharmaceuticals, Inc.

Solesta®
www.solestainfo.com

Solesta®

Brief Summary
Please consult Package Insert for full prescribing information

Indication for Use
Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (eg, diet, fiber therapy, antimotility medications).

Contraindications
Solesta is contraindicated in patients with the following conditions:

- Active inflammatory bowel disease
- Immunodeficiency disorders or ongoing immunosuppressive therapy
- Previous radiation treatment to the pelvic area
- Significant mucosal or full thickness rectal prolapse
- Active anorectal conditions including: abscess, fissures, sepsis, bleeding, proctitis, or other infections
- Anorectal atresia, tumors, stenosis or malformation
- Rectocele
- Rectal varices
- Presence of existing implant (other than Solesta) in anorectal region
- Allergy to hyaluronic acid–based products

Warnings
- Do not inject Solesta intravascularly. Injection of Solesta into blood vessels may cause vascular occlusion.
- Injection in the midline of the anterior wall of the rectum should be avoided in men with enlarged prostate.

Precautions
General precautions
- Solesta should only be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure.
- The safety and effectiveness of Solesta have not been investigated in patients with complete external sphincter disruption or significant chronic anorectal pain.
- The safety and effectiveness of Solesta have not been investigated in patients with previous procedures involving the anorectal region: rectal anastomosis <12 cm from anal verge, anorectal surgery within previous 12 months, hemorrhoid treatment with rubber band within 3 months, anorectal implants and previous injection therapy, Stapled Transanal Rectal Resection (STARR) or stapled hemorrhoidectomy.
- The safety and effectiveness of Solesta have not been studied in patients under the age of 18 years.
- The safety and effectiveness of Solesta have not been studied in pregnant or breastfeeding women.
- The durability of Solesta has not been studied past 12 months.
- The safety and effectiveness of Solesta have been studied in patients who received one or two treatments. In the Pivotal study, the majority of patients received two treatments, four weeks apart.

Patient related precautions
- Patients with bleeding diathesis or patients using anticoagulant or antiplatelet agents, as with any injections, may experience increased bleeding at injection sites.
- Patients should be counseled that a repeated Solesta injection procedure may be required to achieve a satisfactory level of improvement in incontinence.

Procedure related precautions
- Adequate bowel preparation of the rectum using enema is required prior to injection. The enema should be given immediately prior to the procedure to ensure evacuation of the anorectum. It is recommended that additional cleansing of the injection area with an antiseptic be performed prior to injection. Use of prophylactic antibiotics is recommended.
- Solesta should be injected slowly to avoid undue stress on the Luer-lock connection which could cause leakage of the gel.
- After injection of Solesta, hold the needle at the injection site for an additional 15-30 seconds to minimize leakage of Solesta.
- Injections too close to the dentate line or too deep in the sphincter can cause excessive pain.
- Injection should be stopped if excessive bleeding or pain occurs.
- One sterile needle should be used per syringe and injection.

Device related precautions
- The use of needles other than those supplied may impede injection of Solesta due to the properties of the gel and may cause device malfunction.
- Solesta is supplied ready to use in a prefilled syringe with a Luer-lock fitting. Carefully examine the unit to verify that neither the contents nor the package has been damaged in shipment. Do not use if damaged.
- Solesta is supplied sterile and is intended for single use only. Do not re-sterilize, as this may damage or alter the product.
- In the event of accidental contamination of a needle, discard the needle.
- Never mix Solesta with other products.
- Solesta is to be stored at up to 25°C (77°F), and used prior to the expiration date printed on the label. Do not expose Solesta to either sunlight or freezing, as this may damage or alter the product.
- Care should be taken when handling the glass syringes and disposing of broken glass to avoid laceration or other injury.
- After use, syringes and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, state and federal requirements.

Adverse Events

Potential adverse events include: abdominal discomfort, abdominal distension, abdominal pain, lower abdominal pain, abdominal rigidity, alopecia, anal abscess, anal fissure, anal hemorrhage, anal prolapse, anal pruritus, anorectal discomfort, back pain, constipation, C-reactive protein increased, chills, cold sweat, defecation urgency, dermatitis, diarrhea, device dislocation, dizziness, dyspareunia, escherichia bacteremia, fecal incontinence, feces hard, fatigue, gastrointestinal motility disorder, gastrointestinal pain, genital discharge, genital prolapse, hematochezia, hematospermia, hemorrhoids, infection, injection site abscess, injection site discomfort, injection site hemorrhage, injection site hematoma, injection site inflammation, injection site irritation, injection site nodule, injection site pain, injection site pustule, injection site swelling, injection site ulcer, intestinal mass, malaise, mucosal inflammation, musculoskeletal pain, perineal abscess, nausea, edema, pain, painful defecation, pelvic mass, perineal pain, proctalgia, proctitis, pyrexia, rectal abscess, rectal discharge, rectal hemorrhage, rectal lesion, rectal obstruction, rectal prolapse, rectal spasm, rectal tenesmus, rectovaginal septum abscess, urinary retention, vaginal discharge, vulvovaginal pain. The adverse event profile of Solesta beyond 24 months* is not known, but is under investigation in post-market studies.

The safety evaluation of Solesta in the treatment of fecal incontinence (FI) is based on the results from the Pivotal Clinical study, and is supported by the Open-Label multicenter clinical study and one single site Proof-of-Concept study. The analysis of safety was based on the safety cohort of all 206 patients treated in the Pivotal Study with either Solesta or Sham. Safety data for Solesta are available from 359 treatments in 197 total patients followed for up to 18 months post treatment (ie, 136 subjects from the blinded phase and 61 subjects from the open phase).

Directions for Use
Solesta should be administered by qualified physicians with experience in the treatment of anorectal conditions and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure. Solesta should only be used after a thorough physical evaluation of the patient to exclude treatable underlying disorders.

Please consult Package Insert for full directions for use and method of administration.

How Supplied
Solesta is supplied in a glass syringe with a standard Luer-lock fitting containing 1 mL gel. Each syringe is terminally moist heat sterilized in a pouch. Four pouches, each containing one syringe are packed in a carton together with five Sterican needles (21G x 4¾ inches, 0.80 mm x 120 mm), patient record labels and a Package Insert. The needles are sterilized by ethylene oxide.

Storage
Store at a temperature up to 25°C (77°F) and protect from sunlight and freezing.

06/11

*Safety information presented in the Package Insert only includes data up to 18 months

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

Case No. 15-36

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Physicians Healthsource, Inc.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Higgins Benjamin, PLLC 336-273-1600
101 W. Friendly Ave., Ste. 500
Greensboro, NC 27401

DEFENDANTS

Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd. and John Does 1-10

County of Residence of First Listed Defendant Wake
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
47 U.S. C. Sec. 227

Brief description of cause:
Violation of the Telephone Consumer Protection Act

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $ _____

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 1/22/15

SIGNATURE OF ATTORNEY OF RECORD
s/ John F. Bloss

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Physicians Healthsource, Inc.

Plaintiff

v.

Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., and John Does 1-10

Defendant

Civil Action No. 15-36

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Salix Pharmaceuticals, Inc.
8510 Colonnade Center Drive
Raleigh, NC 27615

Also being served, Plaintiff's Motion for Class Action Determination Postponement Pending Discovery & Supporting Brief.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

John F. Bloss
Higgins Benjamin, PLLC
101 W. Friendly Ave., Ste. 500
Greensboro, NC 27401

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Physicians Healthsource, Inc.

Plaintiff

v.

Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., and John Does 1-10

Defendant

Civil Action No. 15-36

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Salix Pharmaceuticals, Ltd.
8510 Colonnade Center Drive
Raleigh, NC 27615

Also being served, Plaintiff's Motion for Class Action Determination Postponement Discovery & Supporting Brief.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

John F. Bloss
Higgins Benjamin, PLLC
101 W. Friendly Ave., Ste. 500
Greensboro, NC 27401

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc: